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10/583,033

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EXAMINER

BRUTUS, JOEL F

ART UNIT

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3768

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,033	Applicant(s) YOSHIKAWA ET AL.	
	Examiner JOEL F. BRUTUS	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 11-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/15/2006 and 5/29/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, Claims 1-8, drawn to an ultrasound motion detecting device classified in class 600, subclass 439.

Group 2, Claims 9-10, drawn to an ultrasound motion detecting device combine with an ultrasound therapeutic device, classified in class 600, subclass 439.

Group 3, Claims 11-17 drawn to an ultrasound motion detecting device combine with an image producing device, classified in class 600, subclass 437.

2. The inventions listed as Groups 2 and 3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The ultrasound detecting device is a subcombination of the combination of claims 9-10 which is the motion detecting device combine with an ultrasound therapeutic device.

The ultrasound detecting device is a subcombination of the combination of claims 11-17 which is the motion detecting device combines with an image producing device.

Therefore, applicant can select one of these two combinations and as mentioned below:

3. During a telephone conversation with Melvin Kraus on 5/20/2009 a provisional election was made without traverse to prosecute the invention of combination group and group 2, claims 1-10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

5. Claim 1 is objected to because of the following informalities: On line 1 "A ultrasonic" should have been "An ultrasonic" and on line 12 ",", should be replaced by ";". Appropriate correction is required.

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanda et al (US Pat: 5,910,118) in view of Shaulov (US Pat: 4,671,293) and/or further In view of Coleman et al (US Pat: 4,932,414)

Regarding claim 1, Kanda et al teaches a diagnostic ultrasound apparatus shown in FIG. 1 comprises an ultrasound probe bilaterally signal-changing between an ultrasound signal and an electric signal and transmitting system circuits and receiving/processing system circuits and uses Doppler detector to measure velocity, blood flow and motion that is pertinent to the claimed invention. The ultrasound probe comprises an array type of piezoelectric transducer arranged at the tip thereof. The transducer has a plurality of piezoelectric elements arranged in an array and arranged in is a scanning direction [see column 4 lines 51-59]. In response to the driving pulses supplied an ultrasound pulse is radiated from each transducer. The ultrasound pulses travel into an object with a transmitting beam formed according to the controlled transmission delay times, and they are partially reflected at boundaries of which acoustic impedance changes, thus providing echoes. The reflected echoes are partially or almost received by the transducers and converted into corresponding electric signals therein [see column 5 lines 1-10].

Kanda et al also teaches the apparatus comprises means for removing a clutter component from the Doppler signal using a characteristic inherently associated with the Doppler signal, the clutter component occurring due to reflection of the ultrasound signal from an organ in the cross section, means for extracting information representing a blood flow passing the cross section based on the Doppler signal of which clutter component is removed by the removing means, and means for displaying the extracted information [see column 3 lines 1-10]. Removing means to subtract a constant value corresponding to the clutter component; estimating means and calculation means [see column 3 lines 5-14].

Kanda et al teaches transmitting an ultrasound signal a plurality of times in each scanning direction composing a cross section to be imaged of an object and receiving an ultrasound echo reflected from along the cross section of the object [see column 3 lines 45-55]. Doppler signal consisting of a train of sequential Doppler data resulting from each spatial sample position in each scanning direction estimating an amount of instantaneous changes in a phase of a clutter component included in the Doppler signal, the clutter component occurring due to reflection of the ultrasound signal from an organ in the cross section correcting a phase of the Doppler signal using the estimated amount of instantaneous changes in the phase subtracting a constant value corresponding to the clutter component from the Doppler signal of which phase is corrected by the correcting means; extracting information representing a blood flow passing the cross section based on the Doppler signal of which clutter component is removed and displaying the extracted information [see column 3 lines 55-67]; and

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echoes reflected from blood flows of extremely lower velocities are distinguishably detected from clutter components in a steady, stable and accurate manner, thus producing two-dimensional-mapped blood flow images of higher detectability [see column 3 lines 63-67].

Kanda et al further teaches the echo signal thus extracted then undergoes estimation of motion states of blood flows (including blood flow velocities, power, and dispersion) and two-dimensional tomographic images are produced on the estimated information [see column 2 lines 9-14]. Kanda et uses a moving target indication (MTI) filter that is formed into a high pass filter, a filtering circuit to extract echo signals reflected from blood flow [see column 2 lines 1-9]. Kanda et al also discusses color flow mapping and reconstructing a CFM image to become a three dimensional volume data [see column 1 lines 37-45]; and further in the three dimensional volume data the same pixel position in a scanned cross section has temporally reception echoes [see column 1 lines 47-50].

Kanda et al doesn't teach a first and a second transducer and a first cross section image are obtained by the first transducer and a second cross section image by a second transducer.

However, Kanda et al teaches an array of transducers comprises a plurality of piezoelectric elements [see column 4 lines 50-55] to transmit waves onto the regions and acquire or producing two dimensional cross section images [see column 2 lines 1-9].

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However, Coleman et al teaches an invention that relates to a system of ultrasonic diagnosis and therapy. In particular, this invention relates to the use of ultrasonics for providing in real-time, cross-sectional and 3-D images of an organ for diagnosis and utilizing the same system to treat disorders by non-invasive means. The invention combines two components, a real-time ultrasonic piezoelectric diagnosis unit and a high intensity, focused therapeutic ultrasonic sub-system [see column 1 lines 9-16]. Coleman et al teaches a display format of the therapeutic beam superimposed on a B-mode image [see column 3 lines 62-64 and fig 4]. Coleman et al teaches obtaining echoes from the tissue under evaluation which are displayed as cross-sectional images on the monitor of the real-time unit. Such a unit is the Coopervision Ultrasonic Digital-B System IV [see column 7 lines 3-10].

However, Shaulov teaches an invention that relates to ultrasonic transducers in general and more particularly to a biplane phased array ultrasonic transducer arrangement having effectively two arrays of ultrasonic oscillators and electrode patterns on opposite major faces of a piezoelectric material, each array consisting of several acoustically separated transducer elements which are electrically controlled to operate independently. The biplane phased array permits the real time imaging of two planar sectors which can be at any relative angle to another [see column 1 lines 8-15].

Therefore, one with ordinary skill in the art would have been motivated to combine these references; by using the biplane phased array ultrasonic transducer as taught by Shaulov transmit waves and acquire echoes and the reconstruction capability to construct plurality of two dimensional cross section images into three dimensional;

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for the purpose of increasing visualization and signal resolution, and to diagnose motion with great accuracy and higher precision. Image in one direction is followed quickly by an image in a second direction, producing a dynamic image of a bodily function [see column 4 lines 27-32].

Regarding claims 2-5, and 7, all other limitations are taught as set forth by the above combination. Kanda et al teaches estimating a motion comprises a speckle component; extracting information representing a blood flow passing the cross section based on the Doppler signal of which clutter component is removed and displaying the extracted information [see column 3 lines 55-67]; and echoes reflected from blood flows of extremely lower velocities are distinguishably detected from clutter components in a steady, stable and accurate manner, thus producing two-dimensional-mapped blood flow images of higher detectability [see column 3 lines 63-67].

Kanda et al doesn't teach first and second transducers acquire a biplane image including two surfaces.

However, Shaulov teaches a biplane phased array transducer for real time medical imaging in at least two sector planes having a composite piezoelectric plate with an array of transducer elements disposed on each major surface of said plate, the array on one side being at an angle to the array on the other side, said transducer elements being defined by dicing each major surface of said composite plate through the conductive electrode surface and into a portion of the composite piezoelectric

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material, and electrical connections provided whereby each array may be grounded alternately so that real time sector imaging in two planes is obtained [see abstract].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine these references; by using a biplane phase array as taught by Shaulov, because biplane phased array is especially useful in cardiac scanning. Simultaneous horizontal and vertical cross sections of the heart will allow the physician to evaluate more effectively the functioning of the heart. The demonstration of low cross talk in composite piezoelectric arrays suggested the application of composite materials to the design of a biplane phased array [see column 1 lines 50-56, Shaulov].

Regarding claim 8, all other limitations are taught as set forth by the above combination. Kanda et al further teaches a method of ultrasound imaging, comprising the steps of transmitting an ultrasound signal a plurality of times in each scanning direction composing a cross section to be imaged of an object and receiving an ultrasound echo reflected from along the cross section of the object; detecting a Doppler signal from a group of echo signals made up of the ultrasound echo received at each time of the plurality of times of the transmission, the Doppler signal consisting of a train of sequential Doppler data resulting from each spatial sample position in each scanning direction estimating an amount of instantaneous changes in a phase of a clutter component included in the Doppler signal, the clutter component occurring due to reflection of the ultrasound signal from an organ in the cross section correcting a phase

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of the Doppler signal using the estimated amount of instantaneous changes in the phase subtracting a constant value corresponding to the clutter component from the Doppler signal of which phase is corrected by the correcting means; extracting information representing a blood flow passing the cross section based on the Doppler signal of which clutter component is removed and displaying the extracted information [see column 3 lines 1-16]. It is known in the art that ultrasound imaging is real time and Kanda et al teaches display means to display information in color [see column 3 lines 19-20].

Regarding claims 9-10, all other limitations are taught as set forth by the above combination.

The above combination doesn't teach an ultrasonic therapeutic device and displaying a biplane image and a three dimensional moving image at the same time.

However, Coleman et al teaches a system for obtaining in real-time cross-sectional and 3-dimensional images of a body under study using ultrasonic energy. A piezoelectric transducer is positioned to emit ultrasonic energy and receive echo pulses. The transducer is electronically swept or physically rotated to produce a series of sectorized scan planes which are separated by a known angular distance. The echo pulses are processed to produce an ultrasonic image in pseudo 3-dimensional display. By using data from one scan plane, processed as a B-scan image, cross-sectional data can be obtained. Such is combined in a display with an overlay to visually portray the

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object and positioning information or comparative data. The system is combined with a computer for data analysis and a therapeutic transducer for treatment [see abstract].

Coleman et al teaches in accordance with this invention, a system is provided that integrates a rapid scan, real-time diagnostic ultrasonic system with a therapeutic ultrasonic system. The real-time diagnostic portion of the system provides three-dimensional and/or cross-sectional images of the tissue under scrutiny in real-time [see column 3 lines 2-7]. The diagnostic transducer may be a single element or an array of elements in one or two dimensions. The therapeutic transducer assembly may also contain a central diagnostic transducer for axial positioning and a central fiber optic system whose projected light beam specifies the central axis of the therapeutic beam [see column 3 lines 11-21].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Kanda, Shaulov and Coleman references by using the therapeutic transducer assembly and the diagnostic transducer and the teaching of a display format that superimpose on a B-mode image [see column 3 lines 62-64] as taught by Coleman; for the purpose of better diagnosing the region of interest to provide an accurate evaluation as to prescribe the best possible treatment.

Regarding claim 6, all other limitations are taught as set forth by the above combination.

The combination is silent to a correlation of a plurality of one dimensional signals of the reflected signals.

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However, Coleman et al teaches the real-time diagnostic portion of the system provides three-dimensional and/or cross-sectional images of the tissue under scrutiny in real-time [see column 3 lines 2-7]. The diagnostic transducer may be a single element or an array of elements in one or two dimensions [see column 3 lines 11-21].

Therefore, one with ordinary skill in the art at the time the invention was made would have known to use an array of transducer in one dimension to obtain a plurality of one dimensional signal as suggested by Coleman et al; because acquire signals in one dimension is useful especially when obtaining translational motion of a moving target.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768